



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 10**

1200 Sixth Avenue, Suite 900  
Seattle, Washington 98101-3140

October 17, 2008

Reply To: OEA 095

**MEMORANDUM**

**SUBJECT:** Summary of Comments from EPA Reviewers on "Draft Risk Assessment Approach for Evaluating Potential Risks from Consuming Breast-Milk for the Portland Harbor Superfund Site"

**FROM:** Dana Davoli  
OEA

**TO:** File

On August 11, 2008, we e-mailed a copy of "Draft Risk Assessment Approach for Evaluating Potential Risks from Consuming Breast-Milk for the Portland Harbor Superfund Site" to the following EPA staff for review:

Dawn Ioven/R3/USEPA/US@EPA, Jacqueline Moya/DC/USEPA/US@EPA, Jon Reid/CI/USEPA/US@EPA, Marian Olsen/R2/USEPA/US@EPA, Milt Clark/R5/USEPA/US@EPA, Stan Barone/DC/USEPA/US@EPA, Nancy Rios-Jafolla/R3/USEPA/US@EPA, Matthew Lorber/DC/USEPA/US@EPA, Daniel Stralka/R9/USEPA/US@EPA, Margaret McDonough/R1/USEPA/US@EPA

We also included a cover letter that provided some background on the PH site and asked for feedback on several specific issues.

On September 11, 2008, a conference call was held to get verbal feedback on the document. All of the EPA reviewers except Daniel Stralka and Margaret McDonough were present. In addition the following EPA Region 10 staff was on the call: Eric Blischke, Michael Cox, Marcia Bailey, and Dana Davoli. The call was separated into two discussions, technical and policy. For the first half of the call on technical issues, Mike Poulsen from ODEQ was present. Written comments were received from only three reviewers, Jacqueline Moya, Matt Lorber (preliminary), and Daniel Stralka.

Below is a summary of the comments received either during the conference call or the in written form:

(A) TECHNICAL ISSUES:

## General

Several reviewers thought the equations and models that we used were appropriate while others questioned if they were realistic. A majority of people thought we should ground-truth the models/equations by comparing our predicted breastmilk PCB concentrations to those found in the literature. The highest PCB concentration measured in breast milk that OR DHS was able to find in the literature was 15 µg/g-lipid, lower than the 24 µg/g-lipid estimated using the example PCB calculation in the PH document (assuming 1 ppm in bass). However, if the decrease in PCB concentrations in breast milk over a year of breastfeeding is included as a part of the PCB example (see below), the PCB concentration estimated in breast milk will be about 18 µg/g-lipid. Some of this information is already provided in the OR DHS/ATSDR letter that was sent to the PH RPMs. This letter included a discussion of the health benefits from breast-feeding, a summary of concentrations of PCBs found in breastmilk in the literature as well as information on effects levels in human studies. We should consider adding some of this information (e.g., literature data on PCB levels in breastmilk) to the PH breastmilk methodology document and include a discussion on what will be done to address the benefits of breastfeeding and the benefits of consuming fish with low contaminant levels. The alternative is to attach the (DHS) Public Health Consultation Letter on Breastfeeding to the methodology document.

The dose to the infant estimated for the PCB example in the PH document is approximately 30 times that of the dose to the mother. This would be expected for not only PCBs but for other bioaccumulative compounds. This estimate is consistent with EPA's Draft Dioxin Reassessment that states that, "*The intake to breast-fed children was estimated to be between 1 and 2 orders of magnitude higher than adults, on a body weight basis.....*" (page 4-39, Volume 2) and with a recent EHP article (Contaminants in Human Milk Weighing the Risks against the Benefits of Breastfeeding, October, 2008) that states that, "*A review by certified nurse-midwife Joanne Jorissen in the October 2007 Advances in Neonatal Care notes that on average, the nursling receives about 50 times (per kilogram of body weight) the daily PCB intake of adults...*"

## Toxicity

Adequacy of the ATSDR intermediate MRL as the toxicity value of choice - There were several question and comments on use of the ATSDR MRL. Several of these came from reviewers who were unfamiliar with the study that the MRL was based upon. For example, questions were raised as to whether the PCB congener mixture tested in monkeys reflected what is actually seen in mother's milk (the mixture used in the monkey study represented 80% of the congeners present in breastmilk in Canadian women, in a proportional mixture) and if the study included both in utero exposure and infant exposure from breastfeeding (the study included exposure to infant monkeys only and did not include in utero exposure).

Other issues raised were:

Does the mixture of PCB congeners used in the monkey study reflect the congeners present at the PH site? For the PH site, the PCB congeners present in fish vary by species and river mile. For example, for small mouth bass, from 44% to 54% of the congener mass is represented by the 15 congeners used in the Rice monkey study. However, the percent contribution of each congener to this mass at PH was often very different than the percent of that congener in the monkey study. For example, PCB congener 118 represented 12.8% of the mass fed to the monkeys, while the percent contribution of this congener to total mass in the PH bass samples ranged from 2.5% to 12.4% by river mile. Although this is an uncertainty for the breastfeeding scenario, it is not unique to this scenario. For example, the cancer and non-cancer chronic risks from consuming fish are calculated using EPA's cancer slope factor and RfD for Aroclors with Aroclor concentrations in fish tissue. This is done despite the fact that the congener pattern in fish tissue vary from site to site and within a site. In addition, data have shown that due to environmental fate and transport issues (e.g., degradation, bioaccumulation) congener patterns in fish do not reflect the congener pattern of the commercial Aroclors used in developing the PCB cancer slope factor and the RfD.

Were the dioxin-like PCB congeners and chlorinated dioxins and furans that might be present at the PH site represented in the toxicity mixture? Does the PCB MRL take into account exposures to dioxin-like toxicity from these compounds? Approximately 24% of the mixture fed to the monkeys was composed of 5 of the dioxin-like PCB congeners: PCB105, PCB118, PCB156, PCB157, and PCB189. The percentage of these 5 congeners in the bass samples at PH ranged from 4.6% to 19% by river mile. Other dioxin-like PCB congeners are present in fish at PH (e.g., ) but were not represented in the mixture fed to the monkeys. The mixture fed to the monkeys also did not include chlorinated dioxins and furans. Therefore, the MRL would not account for exposure to some of the dioxin-like congeners in PH fish nor to the chlorinated dioxins and furans in these fish. Exposure to these compounds at the PH would need to be done using toxicity value specific for 2, 3, 7, 8- TCDD and would add to the risk estimated for PCBs.

### Exposure

As a part of the PH breastmilk document, an example using some of the exposure assumptions from the PH site was presented (e.g., it was assumed that the chemical concentration in fish was 1 ppm and that the fish ingestion rate was 142 g/day). Some reviewers questioned the source of these assumptions, if they were average or high end exposures, and if they were overly conservative. It also was not clear that this was just an example PCB calculation for breastfeeding for this document and that many other exposure routes were being considered in the HHRA for the PH site. To deal with these issues, it may be appropriate to rewrite the PH breastmilk document such that it is not specific for PH, provides more generic guidance for all sites, and is clear that the example provided is just an example.

It was suggested that the expected body burden reduction of PCBs (i.e., concentration of PCBs in mother's milk over the year of breastfeeding) should be moved from the Uncertainty Section to the Risk Characterization. This will be done. This would reduce

the PCB concentration estimated in breast milk from the 24 µg/g-lipid estimated using the example PCB calculation in the PH document (assuming 1 ppm in bass) to about 18 µg/g-lipid.

Dietary intake of PCBs during pregnancy and lactation is only weakly correlated with PCB concentrations in human milk. The more important determinant is long-term consumption of PCBs by the mother. For the PH document, it was assumed that steady-state conditions exist and that maternal intake occurs over a time-period greater than the PCB half-life which is consistent with EPA's Combustion Guidance and with equations 1 through 3(b) in Section 3.4.4.2 of the ATSDR *Toxicological Profile*<sup>5</sup>. Several people pointed out that because of this, the estimates made in the PH document are very sensitive to the half-life assumed for PCBs (7 years in the PH document) as well as to the number of years that the mother is exposed before breast-feeding. It was recommended that these two issues will be specifically addressed in more detail in the Uncertainty Section. More discussion will be included to show how the PCB half-life was chosen and how changes in the half-life affect the calculations. In addition, calculations will be done in the Uncertainty Section to show how reductions in the mother's exposure affect the dose to the infant. For example, if it is assumed that mother is exposed for only 7 years (equivalent to the PCB half life), dose to the infant is reduced by one-half. MIKE, IS THIS CORRECT?

The newly revised human milk chapter of the Child-Specific Exposure Factors Handbook provides data for the EPA recommended children's age groups in mL/day and in mL/kg-day. One reviewer recommended calculating the intake for each age group instead of one average for the 1 year old. Even if the average comes out to be the same, this would show who the most vulnerable age groups are in terms of exposure. This will be done as a part of the Uncertainty discussion. MIKE, SHOULD WE DO THIS IN THE SENSITIVITY ANALYSIS OR IN THE MAIN BODY

### Risk Characterization

Both cancer risk and a hazard quotient were calculated. For the cancer risk, the exposure during one year of breastfeeding was averaged over a lifetime (70 years). There was some concern about the validity of doing cancer risk for such a short duration. MIKE, ARE WE GOING TO LEAVE THIS IN THE DOCUMENT?

### Uncertainty Section

There was a general consensus that this section should be expanded. There was also a suggestion that it include additional sensitivity analyses for several parameters. Some of the issues that merited additional uncertainty discussion were half-life, the mother's exposure in relation to half-life, and site specific data on PCB congeners versus the mixture of congeners fed to the monkeys in the Rice study. It was also recommended that the breastfeeding sections in the latest draft of EPA's dioxin Reassessment be reviewed to determine what other parameters should be discussed in more detail in the Uncertainty Section.

The Uncertainty Section included an example where the non-cancer intake for a child was calculated for seven years of exposure assuming that one year of exposure was from breastfeeding and six years was from fish consumption. The calculated exposure for 7 years on a mg/kg/day basis is lower than that for the one year of breastfeeding. There was some confusion as to why this difference occurs. A suggestion was made that the discussion on this difference be clarified. HQs were then calculated using EPA's RfD with the daily intake from one year of exposure from breastfeeding and seven years of exposure (one year from breastfeeding and 6 from fish consumption). Given our confidence in the use of the ATSDR MRL and the confusion in differences between intakes from a one versus seven year exposure duration, a decision needs to be made whether to include the seven years exposure calculation and comparison of HQs calculated using EPA's RfD. One reviewer also suggested that the intake from 30 years of exposure be calculated to show that the body burden calculated from 30 years would not be significantly different from one year of breastfeeding. This comment shows that additional discussion may be needed in the document to clarify why it is important to calculate the non-cancer risks to breastfeeding infants independent of other exposure scenarios.

#### (B) POLICY AND RISK MANAGEMENT/RISK COMMUNICATION ISSUES

The PH document that was sent out for review did not include the OR DHS/ATSDR letter that was sent to the PH RPMs as we were primarily concerned with comments on the methodology and parameters used to calculate intake from breastfeeding and the cancer and non-cancer risks. The OR DHS/ATSDR letter included a discussion of the health benefits from breast-feeding, a summary of concentrations of PCBs found in breastmilk in the literature as well as information on effects levels in human studies. Recommendations were also made for a community outreach program.

Comments from the reviewers included the following:

Although the methodology and most of the exposure parameters for the mother's milk pathway are in existing EPA guidance, there was concern that adding this scenario to Superfund and RCRA risk assessments is precedence setting. Because of this, some of the reviewers suggested that we should consider having the document peer reviewed and that we ask for input from other EPA programs. It wasn't clear how we could ask for peer review and program input on guidance that EPA has already published (e.g., U. S. EPA Human Health Risk Assessment Protocol for Hazard Waste Combustion Facilities (Combustion Guidance), U.S. EPA. Child-Specific Exposure Factors Handbook) and that has been used for several years to assess risks, at least for hazardous waste combustion incinerators. We are not proposing the use of any new methods but rather extending the combustion guidance to assessment of the breastmilk pathway at other hazardous waste sites.

Several reviewers were concerned about the risk communication issues and outreach related to this pathway including the need to discuss the benefits from breastfeeding and

from consumption of fish with low contaminant levels. We recognized this as a major concern and are proposing to deal with it by requiring that the benefits of breastfeeding be included in the risk assessment and by working with OR DHS in developing a community outreach campaign directed toward girls and women of child-bearing age who are high fish consumers. These issues were not included in the PH mother's milk methodology document so it was not clear that we had considered them. It may be useful to include a summary in the breastmilk methodology document of the risk-benefit discussion in OR DHS/ATSDR as well as a summary of the recommended outreach activities or to include the OR DHS Public Health Consultation Letter on Breastfeeding to the methodology paper.

Given the concern with the risk communication issues and the fact that this pathway will not drive the remedial goal for the PH site, Eric Blischke asked whether there is really a need to include this pathway, at least in the PH HHRA. This is a separate question from a decision to develop Region 10 OEA guidance on the breastmilk pathway that would be used for all Superfund and RCRA sites. For some sites, this pathway may be the driver for remediation.